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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,542	11/30/2001	John D. McNeish	PCI0897ADAM	1000

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07/28/2004

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,542

Applicant(s)

MCNEISH ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04/24/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/24/2004 has been entered.

The amendment filed 05/24/2004 is under current consideration. Claims 2,4,5 and 8-14 have been cancelled. Claims 1,6, and 7 have been amended. Claims 1,3,6 and 7 are pending and under current consideration.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse whose genome comprises a homozygous disruption in the RAMP1 gene wherein said mouse exhibits elevated aminotransferase activity, elevated alanine aminotransferase activity or elevated creatine kinase activity, does not reasonably provide enablement for a genetically modified mouse wherein the mouse is mosaic. The specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and /or use the invention commensurate in scope with these claims.

Claims 1 and 3 are directed to a genetically-modified mouse comprising a homozygous disruption in the RAMP1 gene where the mouse exhibits elevated aminotransferase activity, elevated alanine aminotransferase activity or elevated creatine kinase activity. Claim 3 limits the disruption to one made such that a reporter gene is brought under the control of the RAMP1 regulatory sequences. Claim 6 is drawn to cells isolated from the mouse.

The breadth of claim 1 is such that it encompasses both a transgenic mouse wherein all somatic and germ cells comprise a disruption in the RAMP1 gene and a genetic mosaic mouse wherein only a portion of the cells of the mouse comprise the gene disruption. The specification has taught that transgenic mice wherein all somatic and germ cells comprise a disruption in the RAMP1 gene exhibit elevated aminotransferase activity, elevated alanine aminotransferase activity or elevated creatine kinase activity. The specification has not taught a phenotype for the genetic mosaic mice encompassed by the claims. As set forth in the previous office action mailed 06/18/2003, the phenotype of stable transgenic knockout mice is unpredictable (see paragraph bridging pages 6-7; refer to Leonard, 1995; Griffiths, 1998). The phenotype of genetic mosaic knockouts is made further unpredictable as a result of the inability to control the number or location of genetically altered cells within the mosaic mouse. Therefore, in light of this unpredictability, one of skill in the art could not predict, with any reasonable degree of success, what the phenotype of the mosaic mouse encompassed by the claims would be. As a result, the skilled artisan would not know how to use the mosaic mouse without undue experimentation to

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determine the phenotype and use. Therefore, claims should be limited to a transgenic mouse whose genome comprises a homozygous disruption of the RAMP1 gene.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is unclear as it is drawn to a genetically-modified cell isolated from the mouse of claim 1. It is not clear if the claimed cell is further genetically-modified after isolation from the mouse or if the term is refer to the original genetic modification of the RAMP1 gene in the mouse. If the latter is the case, then directing the claim a mouse cell isolated from the mouse of claim 1 would be more clear.

Claim 7 is unclear because it recites that the cell is capable of generating a mouse. It is unclear whether this characteristic actually occurs or that the cell could potentially generate a mouse. "Capable of" implies a latent property and the conditions for the latent property must be clearly defined. Therefore, it is unclear if the latent property is ever obtained.

Claim 7 is unclear because it refers to a cell generating a progeny mouse. The progeny of a cell is a cell. In the instant case, a mouse ES cell gives rise to a mouse.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725.

The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630

Valarie Bertoglio
Examiner
Art Unit 1632